

DECLARATION OF COMPLIANCE

Fuente II Filter Cartridges

AB Style “W” Code

Cartridge Part Numbers



This is a guide to the part numbering structure only. For specific options, please contact Pall.

Table 1 : Nominal Length

| Code | Description |
|------|---------------|
| 1 | 254 mm (10") |
| 2 | 508 mm (20") |
| 3 | 762 mm (30") |
| 4 | 1016 mm (40") |

Table 2 : Adaptor

| Code | Description |
|------|--|
| 3 | SOE – single open end with flat closed end and external 222 O-rings |
| 7 | SOE – single open end with fin end, 2 locking tabs and external 226 O-rings |
| 8 | SOE - single open end - with fin closure end and external 222 O-Rings on open end. |
| 28 | SOE – single open end with fin end, 3 locking tabs and external 222 O-rings |

Table 3 : O-ring Seal Material

| Code | Description |
|------|---------------------------|
| H4 | Silicone Elastomer |
| J | Ethylene Propylene Rubber |

Fuente II polyethersulfone membrane filter cartridges are a unique combination of Ultipleat® filter construction and optimized built-in pre-filtration to give longer filter life and lower filtration costs.

Fuente II filter cartridges are intended for use in food and beverage water filtration applications.

An initial flush is required prior to use.

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Fuente II Filter Cartridges (AB Style “W” Code)

Components

| | |
|---------------------------------|---|
| Filter Media | Hydrophillic Supor* polyethersulfone membrane |
| Support / Drainage | Polypropylene |
| Cage, Core, End Cap and Fin End | Polypropylene |
| Adaptor | Polypropylene with internal stainless steel reinforcing ring as appropriate to design |
| O-ring Seal | Ethylene Propylene Rubber (J) and Silicone Elastomer (H4) |

Declaration

Fuente II AB style “W” Code style filter cartridges comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

Europe

The “W” Code Fuente II filter cartridges meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

Our suppliers’ information indicates that the polymeric materials used to produce “W” Code Fuente II filter cartridges are made from monomers and additives consistent with Annex I of European Regulation (EU) number 10/2011, and its amendments, relating to plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

OML and SML migration testing of cartridges (excluding seals) has been performed and met migration criteria after flushing and in flow conditions, in:

- Simulant A (10 % ethanol) 2 hours at reflux,
- Simulant B (3% acetic acid) 2 hours at reflux,
- Simulant D1 (50% ethanol) 2 hours at reflux,
- And water up to 70 °C (158 °F).

Note: This product contains materials that are subject to Specific Migration Limit (SML) requirements. This product contains calcium stearate, which is approved as a direct food additive.

French requirements for food contact elastomers (Arrêté of 9th November 1994 amended by order of 5th August 2020) Typical samples of the ‘H4’ (Silicone) and ‘J’ (EPDM) seal material formulations have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 20 % ethanol, 50 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the ‘S’ O-rings, under the test conditions, were well within the limit for all migration fluids tested. The data obtained with the ‘J’ O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid, 20 % ethanol and 50 % ethanol. The ‘J’ O-rings are not suitable for use in fatty foods.

German requirements for food contact elastomers (BfR XV Silicones) Typical samples of the ‘H4’ (Silicone) seal material formulation have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 10 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the ‘S’ O-rings, under the test conditions, were well within the limit for all migration fluids tested.

German requirements for food contact elastomers (BfR XXI Natural and Synthetic Rubber Category 1) Typical samples of the ‘J’ (EPDM) seal material formulation have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 10 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the ‘E’ O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid and 10 % ethanol. The ‘E’ O-

rings are not suitable for use in high alcohol or fatty foods. Additionally, our supplier states that this O-ring seal formulation is suitable for food contact use under BfR XXI category 4.

Users should satisfy themselves that these materials are suitable for use in their specific food application.

Mercosur

The materials of construction meet the requirements for food contact as detailed in Reglamento Técnico Mercosur sobre materiales lista positiva de

- monómeros, otras sustancias de partida y polímeros autorizado para la elaboración de envases y equipamientos plásticos in contacto con alimentos, Mercosur/GMC/Res. No. 19/21 y
- aditivos para materiales plásticos destinados a la elaboración de envases y equipamientos in contacto con alimentos, Mercosur/GMC/Res. No. 56/92.

People's Republic of China

The “W” Code Emflon PFRW AB style filter cartridges meet the requirements for food contact as detailed in Chinese standard Numbers GB 4806.7-2023 and GB 4806.11.

USA

The materials of construction meet the FDA requirements for food contact use as detailed in Code of Federal Regulations, 21 CFR paragraphs 170-199 in that:

- Silicone Elastomeric seal material to 21 CFR section 177.2600 (Rubber articles intended for repeated use)
- Silicone Elastomeric seal material used conforms to 3-A Sanitary Standards 18-03 Class I for use with milk / butter oil products.
- Ethylene Propylene Rubber seal material to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils)
- Polypropylene to 21 CFR section 177-1520 (Olefin polymers).
- Examples of Supor membranes were analyzed as per ASTM test method for conformance to FDA specifications for food contact substance. The membrane met the specifications of polyethersulfone resins as detailed in Title 21 of the US Code of Federal Regulations 177.2440 paragraphs (a), (b) and (c) including acceptable heavy metal content. Additionally, no specified or known adjuvants were detected at a limit of 0.001 %.

While it is the responsibility of the user to determine the safety of equipment and materials for food contact applications, the data indicate that the composition of the Supor membranes are suitable for food contact since under the test conditions, no substances were detected that are not permitted as components of food contact substances.

Note: this product may contain trace levels of titanium dioxide, a chemical known to the state of California to cause cancer. The listing for titanium dioxide is for “airborne, unbound particles or respirable size.” The listing is not applicable to titanium dioxide within a product matrix such as polypropylene.

Process Quality System

Sites of Manufacture: Pall Filtersystems GmbH, Bad Kreuznach, Germany supplied by Pall Sàrl. Made in Germany.

The Quality Management System at Pall Filtersystems GmbH, Bad Kreuznach are certified to ISO 9001:2015.

These products / product packaging carry a lot number / date code to facilitate traceability to suppliers' materials and Pall production records.

Pall Filtersystems GmbH confirms that the product manufacturing environment is in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

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Pall Corporation has offices and plants throughout the world. To locate the Pall office or distributor nearest you, visit www.pall.com/contact.

The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

IF APPLICABLE Please contact Pall Corporation to verify that the product conforms to your national legislation and/or regional regulatory requirements for water and food contact use..

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